Procedure file

Basic information DEC - Discharge procedure 2020/2157(DEC) Procedure completed 2019 discharge: European Medicines Agency (EMA) Subject 8.70.03.09 2019 discharge

Key players			
European Parliament	Committee responsible CONT Budgetary Control	Rapporteur	Appointed 08/09/2020
		ECR CZARNECKI Ryszard	
		Shadow rapporteur	
		CHRISTOFOROU Lefteris	
		RÓNAI Sándor	
		europe. CSEH Katalin	
		EICKHOUT Bas	
	Committee for opinion ENVI Environment, Public Health and Food Safety	Rapporteur for opinion	Appointed 10/09/2020
		renew europe. CANFIN Pascal	
European Commission	Commission DG	Commissioner	
	Budget	HAHN Johannes	

Key events			
29/06/2020	Non-legislative basic document published	COM(2020)0288	
15/09/2020	Committee referral announced in Parliament		
22/03/2021	Vote in committee		
30/03/2021	Committee report tabled for plenary	A9-0073/2021	
27/04/2021	Debate in Parliament	-	

28/04/2021	Decision by Parliament	T9-0181/2021	Summary
24/09/2021	Final act published in Official Journal		

Technical information		
Procedure reference	2020/2157(DEC)	
Procedure type	DEC - Discharge procedure	
Stage reached in procedure	Procedure completed	
Committee dossier	CONT/9/03872	

Documentation gateway					
Non-legislative basic document		COM(2020)0288	29/06/2020	EC	
Committee draft report		PE657.226	14/01/2021	EP	
Committee opinion	ENVI	PE660.255	01/02/2021	EP	
Supplementary non-legislative basic document		05793/2021	05/02/2021	CSL	
Amendments tabled in committee		PE680.787	04/03/2021	EP	
Committee report tabled for plenary, single reading		A9-0073/2021	30/03/2021	EP	
Text adopted by Parliament, single reading		<u>T9-0181/2021</u>	28/04/2021	EP	Summary

Final act

Budget 2021/1583 OJ L 340 24.09.2021, p. 0243

2019 discharge: European Medicines Agency (EMA)

The European Parliament decided by 580 votes to 79, with 39 abstentions, to grant discharge to the Executive Director of the European Medicines Agency (EMA) for the financial year 2019 and to approve the closure of the accounts for that year.

Noting that the Court of Auditors has stated that it has obtained reasonable assurance that the Agency's annual accounts for the financial year 2019 are reliable and that the underlying transactions are legal and regular, Parliament adopted, by 607 votes to 79 with 7 abstentions, a resolution containing a series of recommendations which form an integral part of the discharge decision and which complement the general recommendations set out in the resolution on the performance, financial management and control of EU agencies.

Agencys financial statements

The Agency's final budget for the year 2019 was EUR 346 762 000, which represents an increase of 2.66% compared to 2018. In 2019, 85.70% of the Agency's revenue came from fees paid by the pharmaceutical industry for services provided.

Budgetary and financial management

Members noted with satisfaction the budget monitoring efforts during 2019 which resulted in a budget execution rate of 98.56%, which is an increase of 9.42% compared to 2018. The implementation rate of payment appropriations was 83.05%, which represents an increase of 9.41% compared to 2018.

Other observations

Members also made a series of observations concerning performance, staff, procurement, conflicts of interest and internal controls.

In particular, they noted that:

- the Agency uses a number of key performance indicators, including a set of operational, management and governance, communication and stakeholder indicators, to measure the implementation of its work programme and stakeholder satisfaction, as well as to assess the added value of its activities;
- the Agency cooperates with other agencies on joint scientific contributions and exchanges scientific data. It continues to have working arrangements with the European Centre for Disease Prevention and Control, the European Food Safety Authority, the European Chemicals

Agency and the European Monitoring Centre for Drugs and Drug Addiction;

- the Agency plays an important role in the protection and promotion of public and animal health through the evaluation and monitoring of medicinal products for human and veterinary use. In 2019, it recommended 81 new medicinal products for marketing authorisation (66 for human use and 15 for veterinary use), including 35 new active substances (30 for human use and 5 for veterinary use);
- on 31 December 2019, the establishment plan was 98.65 % implemented, with 583 temporary agents appointed out of 591 temporary agents authorised under the Union budget (compared to 591 posts authorised in 2018). The lack of gender balance in the Agency's senior management is a matter of concern, as is the large size of the Management Board;
- the Agency's procurement and planning procedures, including the use of temporary and external staff, need to be improved;
- no internal whistleblowing cases were reported, but 20 external whistleblowing cases were identified. 4 cases were closed, of which 13 were opened in 2019 and 11 in previous years, and 7 cases are still ongoing. No cases of conflict of interest were reported by the Agency;
- following the move to Amsterdam on 30 March 2019, the Agency entered into an agreement with its landlord to sublet its former office premises to a sub-tenant on terms consistent with the terms of the head lease. The sub-lease agreement runs until the expiry of the Agency's lease in 2039. As the Agency remains bound by the lease agreement, it could be held liable for the entire amount remaining payable under the rental contract if the subtenant fails to meet its obligations.

Parliament welcomed the Agency's efforts to strengthen its transparency policy regarding COVID-19 medicines and vaccines. It urged the Agency to publish data from clinical trials before marketing authorisation and failing that, in a timely manner.